



No. 09/966,783

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1. (Currently Amended): A method for sterilizing drug coated medical devices, the method comprising the steps of:

positioning at least one packaged, drug coated medical device in a sterilization chamber;
creating a vacuum in the sterilization chamber, the drug comprising a compound that inhibits mTOR and binds FKBP12;

creating a vacuum in the sterilization chamber;

increasing and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the sterilization chamber in the range from about forty percent to about eighty-five percent for a first predetermined period;

injecting a sterilization agent at a predetermined concentration into the sterilization chamber and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the range from about forty percent to about eighty-five percent for a second predetermined period; and

removing the sterilization agent from the sterilization chamber through a plurality of vacuum and nitrogen washes over a third predetermined period, the temperature in the sterilization chamber being maintained at a temperature in the range from about thirty degrees C to about forty degrees C.

Claim 2. (Original): The method for sterilizing drug coated medical devices according to Claim 1, wherein the step of creating a vacuum includes reducing the pressure in the sterilization chamber to under approximately ten kPa.

Claim 3. (Original): The method for sterilizing drug coated medical devices according to Claim 2, wherein the first predetermined period of time is approximately three hours.

Claim 4. (Original): The method for sterilizing drug coated medical devices according to Claim 3, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about two-hundred mg/l to about one thousand two hundred mg/l and the second predetermined period of time is approximately six hours.

Claim 5. (Original): The method for sterilizing drug coated medical devices according to Claim 4, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about eight-hundred mg/l to about nine hundred fifty mg/l and the second predetermined period of time is approximately six hours.

Claim 6. (Original): The method for sterilizing drug coated medical devices according to Claim 5, wherein the step of removing the sterilization agent from the sterilization chamber includes a series of alternating vacuum and nitrogen injection stages and the third predetermined period of time is in the range from about two hours to about forty-eight hours.

Claim 7. (Original): The method for sterilizing drug coated medical devices according to Claim 1, wherein the method further comprises the step of removing the sterilization agent from the at least one packaged, drug coated medical device.

Claim 8. (Original): The method for sterilizing drug coated medical devices according to Claim 7, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about one hour to about two weeks.

Claim 9. (Original): The method for sterilizing drug coated medical devices according to Claim 8, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about twelve hours to about seven days.

Claim 10. (Original): The method for sterilizing drug coated medical devices according to Claim 1, wherein the drug coated medical device comprises:

a biocompatible vehicle affixed to at least a portion of the medical device; and

at least one agent in therapeutic dosages incorporated into the biocompatible vehicle.

Claim 11. (Original): The method for sterilizing drug coated medical devices according to Claim 10, wherein the polymeric matrix comprises poly(ethylene-co-vinylacetate) and polybutylmethacrylate.

Claim 12. (Original): The method for sterilizing drug coated medical devices according to Claim 10, wherein the polymeric matrix comprises first and second layers, the first layer making contact with at least a portion of the medical device and comprising a

solution of poly(ethylene-co-vinylacetate) and polybutylmethacrylate, and the second layer comprising polybutylmethacrylate.

Claim 13. (Original): The method for sterilizing drug coated medical devices according to Claim 12, wherein the at least one agent is incorporated into the first layer.

Claim 14. (Original): The method for sterilizing drug coated medical devices according to Claim 10, wherein the biocompatible vehicle comprises a polyfluoro copolymer comprising polymerized residue of a first moiety selected from the group consisting of vinylidene fluoride and tetrafluoroethylene, and polymerized residue of a second moiety other than the first moiety and which is copolymerized with the first moiety, thereby producing the polyfluoro copolymer, wherein the relative amounts of the polymerized residue of the first moiety and the polymerized residue of the second moiety are effective to produce the biocompatible coating with properties effective for use in coating implantable medical devices when the coated medical device is subjected to a predetermined maximum temperature, and a solvent in which the polyfluoro copolymer is substantially soluble.

Claim 15. (Original): The method for sterilizing drug coated medical devices according to Claim 14, wherein the polyfluoro copolymer comprises from about 50 to about 92 weight percent of the polymerized residue of the first moiety copolymerized with from about 50 to about 8 weight percent of the polymerized residue of the second moiety.

Claim 16. (Original): The method for sterilizing drug coated medical devices according to Claim 14, wherein said polyfluoro copolymer comprises from about 50 to about 85 weight percent of polymerized residue of vinylidene fluoride copolymerized with from about 50 to about 15 weight percent of the polymerized residue of the second moiety.

Claim 17. (Original): The method for sterilizing drug coated medical devices according to Claim 14, wherein the copolymer comprises from about 55 to about 65 weight percent of the polymerized residue of the vinylidene fluoride copolymerized with from about 45 to about 35 weight percent of the polymerized residue of the second moiety.

Claim 18. (Original): The method for sterilizing drug coated medical devices according to Claim 14, wherein the second moiety is selected from the group consisting of hexafluoropropylene, tetrafluoroethylene, vinylidene fluoride, 1-hydropentafluoropropylene, perfluoro (methyl vinyl ether), chlorotrifluoroethylene, pentafluoropropene, trifluoroethylene, hexafluoroacetone and hexafluoroisobutylene.

Claim 19. (Original): The method for sterilizing drug coated medical devices according to Claim 14, wherein the second moiety is hexafluoropropylene.

Claim 20. (Currently Amended): A method for sterilizing drug coated medical devices, the method comprising the steps of:

loading the at least one packaged, drug coated medical device in a preconditioning chamber, the drug comprising a compound that inhibits mTOR and binds FKBP12, the preconditioning chamber being maintained at a first predetermined temperature and a first predetermined relative humidity for a first predetermined time period;

positioning at least one packaged, drug coated medical device in a sterilization chamber;

creating a vacuum in the sterilization chamber;

increasing and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the sterilization chamber in the range from about forty percent to about eighty-five percent for a second predetermined period;

injecting a sterilization agent at a predetermined concentration into the sterilization chamber and maintaining the temperature in the sterilization chamber in the range from about twenty-five degrees C to about thirty-five degrees C and the relative humidity in the range from about forty percent to about eighty-five percent for a third predetermined period; and

removing the sterilization agent from the sterilization chamber through a plurality of vacuum and nitrogen washes over a fourth predetermined period, the

temperature in the sterilization chamber being maintained at a temperature in the range from about thirty degrees C to about forty degrees C.

Claim 21. (Original): The method for sterilizing drug coated medical devices according to Claim 20, wherein the step of loading the at least one packaged, drug coated medical device in a preconditioning chamber, includes maintaining the temperature in the range from about ten degrees C to about seventy degrees C, the relative humidity in the range from about twenty percent to about ninety-five percent for a period of time ranging from about one hour to about five days.

Claim 22. (Original): The method for sterilizing drug coated medical devices according to Claim 21, wherein the step of loading the at least one packaged, drug coated medical device in a preconditioning chamber, includes maintaining the temperature in the range from about twenty-seven degrees C to about thirty-two degrees C, the relative humidity in the range from about fifty percent to about seventy percent for a period of time ranging from about five hours to about seven hours.

Claim 23. (Original): The method for sterilizing drug coated medical devices according to Claim 22, wherein the step of creating a vacuum includes reducing the pressure in the sterilization chamber to under approximately ten kPa.

Claim 24. (Original): The method for sterilizing drug coated medical devices according to Claim 23, wherein the first predetermined period of time is approximately three hours.

Claim 25. (Original): The method for sterilizing drug coated medical devices according to Claim 24, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about two-hundred mg/l to about one thousand two hundred mg/l and the second predetermined period of time is approximately six hours.

Claim 26. (Original): The method for sterilizing drug coated medical devices according to Claim 25, wherein the step of injecting a sterilization agent into the sterilization chamber comprises injecting gaseous ethylene oxide at a concentration in the range from about eight-hundred mg/l to about nine-hundred fifty mg/l and the second predetermined period of time is approximately six hours.

Claim 27. (Original): The method for sterilizing drug coated medical devices according to Claim 26, wherein the step of removing the sterilization agent from the sterilization chamber includes a series of alternating vacuum and nitrogen injection stages and the third predetermined period of time is in the range from about two hours to about forty-eight hours.

Claim 28. (Original): The method for sterilizing drug coated medical devices according to Claim 20, wherein the method further comprises the step of removing the sterilization agent from the at least one packaged, drug coated medical device.

Claim 29. (Original): The method for sterilizing drug coated medical devices according to Claim 28, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

- removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

- circulating ambient air through the controlled environment; and

- maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about one hour to about two weeks.

Claim 30. (Original): The method for sterilizing drug coated medical devices according to Claim 29, wherein the step of removing the sterilization agent from the at least one packaged, drug coated medical device comprises the steps of:

removing the at least one packaged, drug coated medical device from the sterilization chamber and positioning the at least one packaged, drug coated medical device in a controlled environment;

circulating ambient air through the controlled environment; and

maintaining the temperature in the controlled environment in the range from about ten degrees C to about seventy degrees C, the at least one packaged, drug coated medical device is maintained in the controlled environment for a length of time in the range from about one hour to about two weeks.

Claim 31. (Original): The method for sterilizing drug coated medical devices according to Claim 20, wherein the drug coated medical device comprises:

a biocompatible vehicle affixed to at least a portion of the medical device; and

at least one agent in therapeutic dosages incorporated into the biocompatible vehicle.

Claim 32. (Original): The method for sterilizing drug coated medical devices according to Claim 20, wherein the polymeric matrix comprises poly(ethylene-co-vinylacetate) and polybutylmethacrylate.

Claim 33. (Original): The method for sterilizing drug coated medical devices according to Claim 20, wherein the polymeric matrix comprises first and second layers, the first layer making contact with at least a portion of the medical device and comprising a solution of poly(ethylene-co-vinylacetate) and polybutylmethacrylate, and the second layer comprising polybutylmethacrylate.

Claim 34. (Original): The method for sterilizing drug coated medical devices according to Claim 33, wherein the at least one agent is incorporated into the first layer.

Claim 35. (Original): The method for sterilizing drug coated medical devices according to Claim 20, wherein the biocompatible vehicle comprises a polyfluoro copolymer comprising polymerized residue of a first moiety selected from the group consisting of vinylidene fluoride and tetrafluoroethylene, and polymerized residue of a second moiety other

than the first moiety and which is copolymerized with the first moiety, thereby producing the polyfluoro copolymer, wherein the relative amounts of the polymerized residue of the first moiety and the polymerized residue of the second moiety are effective to produce the biocompatible coating with properties effective for use in coating implantable medical devices when the coated medical device is subjected to a predetermined maximum temperature, and a solvent in which the polyfluoro copolymer is substantially soluble.

Claim 36. (Original): The method for sterilizing drug coated medical devices according to Claim 35, wherein the polyfluoro copolymer comprises from about 50 to about 92 weight percent of the polymerized residue of the first moiety copolymerized with from about 50 to about 8 weight percent of the polymerized residue of the second moiety.

Claim 37. (Original): The method for sterilizing drug coated medical devices according to Claim 35, wherein said polyfluoro copolymer comprises from about 50 to about 85 weight percent of polymerized residue of vinylidene fluoride copolymerized with from about 50 to about 15 weight percent of the polymerized residue of the second moiety.

Claim 38. (Original): The method for sterilizing drug coated medical devices according to Claim 35, wherein the copolymer comprises from about 55 to about 65 weight percent of the polymerized residue of the vinylidene fluoride copolymerized with from about 45 to about 35 weight percent of the polymerized residue of the second moiety.

Claim 39. (Original): The method for sterilizing drug coated medical devices according to Claim 35, wherein the second moiety is selected from the group consisting of hexafluoropropylene, tetrafluoroethylene, vinylidene fluoride, 1-hydropentafluoropropylene, perfluoro (methyl vinyl ether), chlorotrifluoroethylene, pentafluoropropene, trifluoroethylene, hexafluoroacetone and hexafluoroisobutylene.

Claim 40. (Original): The method for sterilizing drug coated medical devices according to Claim 35, wherein the second moiety is hexafluoropropylene.